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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,494	03/07/2002	Joseph M. Patti	P06331US02/BAS	2645

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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 05/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/091,494	PATTI ET AL.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,11-37 and 41-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *42-53* is/are allowed.

6)☒ Claim(s) *1-3,11-37,41 and 54-56* is/are rejected.

7)☒ Claim(s) *12-21,30-35,41 and 54* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.O.O.

DETAILED ACTION

Amended or new claims 1-3, 11-37, 41-56 are pending.
The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Allowable Subject Matter

1. Claims 42-53 define over the prior art of record and therefore define allowable subject matter and in light of In re Ouchii and Brauer (a method of making the allowed product(s) of US Pat. 6,692,739).

Rejections Withdrawn

1. Rejections and objections over canceled claims are withdrawn, specifically claims 5, 7-10 and 38-40.
2. The rejections of claims 11,22,29 and 36 under obviousness type double patenting have been obviated through submission of an effective terminal disclaimer.

Objections/Rejections Maintained

3. Claims 18-21 objected to as being dependent upon a rejected base claim is maintained for reasons of record and are now rejected under 35 USC 112, first paragraph (new matter) as set forth below based upon the newly submitted amended claim limitations.
4. Amended claims 22, 29, and 36 rejected under 35 USC 102(e) as being anticipated by Foster et al (US Pat. 6,008,341) is maintained for reasons of record and responses set forth below.
5. Amended claims 11, 22, 29 and 36 rejected under 35 USC 102(e) as being anticipated by Gristina et al (US Pat. 5,718,899 or 5,707,627) for reasons of record and responses set forth below.
6. Amended claims 1-3,12-17, 22-37, 41 and new claims 54-56 are rejected under 35 USC 103(a) as not being patentable over Hook et al (US Pat. 6,288,214), is maintained for reasons of record and responses set forth below.

Response to Arguments

7. The objection to claims 18-21 for being dependent upon a rejected base claim is maintained for reasons of record as they were not amended into independent form and no traversal was set forth in Applicant's remarks and are now rejected under 35 USC 112, first

paragraph (new matter) as set forth below based upon the newly submitted amended claim limitations.

8. The rejection of claims 22, 29, and 36 under 35 USC 102(e) as being anticipated by Foster et al (US Pat. 6,008,341) is traversed on the grounds that the claims have been amended to be directed to human immunoglobulin.

9. It is the position of the examiner that *upon reconsideration* of the disclosure of Foster et al, the reference in fact was found to constructively reduce their invention to practice to include polyclonal and monoclonal antibodies raised against the fibrinogen binding protein or its binding domain obtained by vaccinating humans (see Uses of the invention, col. 10, lines 56-67). Therefore, the examiner's prior comment that the reference does not teach human immunoglobulin did not encompass the full teachings of Foster et al who does disclose compositions of polyclonal and monoclonal antibodies obtained through administration of humans with a vaccine compositions to humans, the compositions comprising Staphylococcus aureus fibrinogen binding protein or its binding region domain and teaches the antibodies obtained through immunization to provide protection against infection by blocking Staphylococcal adherence (see col. 11, uses of antibodies numbers 4-6 and 10). The Foster et al reference does disclose human immunoglobulin (antibodies) that are raised against S.aureus fibrinogen binding protein.

10. The rejection of claims 11, 22, 29 and 36 under 35 USC 102(e) as being anticipated by Gristina et al (US Pat. 5,718,899 or 5,707,627) is traversed on the grounds US Patent 5,496,706

to Kuusela found 11 out of 79 strains of S.aureus to be negative for clumping factor and protein A.

11. It is the position of the examiner that the applied reference was either one of US Pat. 5,718,899 or 5,707,627 to Gristina et al and not Kuusela and Gristina et al is directed to the production and administration of human immunoglobulins that will inhibit bacterial infection, to include Staphylococcous aureus (see Table 7, col. 11, lines 43-45 and col. 12, lines 55-57) that are combined with human immunoglobulins for Staphylococcus epidermidis. The claims are not directed to compositions that comprise antibodies to both clumping factor and protein A, but to clumping factor and additional adhesions of Staphylococcus epidermidis and S. aureus. Gristina et al disclose compositions of human immunoglobulins (hyperimmune immunoglobulin, col. 12, lines 8-9 and Table 7) that are directed to staphylococcal adhesion so they will block adherence (see col. 7, lines 3-5; col. 10, lines 33-34) and prevent adherence (see col. 9, line 5). Functionally the human immunoglobulin compositions of Gristina et al blocked binding of Staphylococcus aureus and epidermidis from adhering to surfaces through specific binding of the adhesins on the surface of the bacteria. While the surface proteins were not characterized, the polyclonal immunoglobulins inherently were directed to the virulence adhesins on the surface of S. aureus and S.epidermidis which include clumping factor, and other Sdr proteins. No specific evidence has been provided to show the pathogenic adhesion positive strains of Gristina et al did not comprise clumping factor and other Sdr proteins which would produce a polyclonal human immunoglobulin composition as now claimed.

12. Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on applicant to show a novel or unobvious

difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594. Inherently the reference anticipates the now claimed invention.

13. Atlas Powder Co. V IRECA, 51 USPQ2d 1943, (FED Cir. 1999) states Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior arts functioning, does not render the old composition patentably new to the discoverer. The Court further held that Athis same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art. The rejection is maintained for reasons of record and responses set forth above.

14. The rejection of amended claims 1-3,12-17, 22-37, 41 and new claims 54-56 under 35 USC 103(a) as not being patentable over Hook et al (US Pat. 6,288,214), is traversed on the grounds that the Hook patent does not disclose human immunoglobulin compositions of high titers to specific staphylococcal adhesins, nor provide any motivation or suggestion to do so and that the examiner points to unrelated parts of the reference in order to assert that Applicant's claims are obvious.

15. It is the position of the examiner that Hook et al teaches the importance of passive immunization (see section 4.16) directed against adhesions from multiple bacteria (see section 4.22 "mix and match"), and specifically teaches the combination of immunoglobulin

compositions directed against S.aureus and S.epidermidis (see section 4.24.1) as they have been found to cause from 1/3 to ½ of all cases of sepsis.

16. Hook et al teaches the importance of preventing adherence of bacterial pathogens associated with adhesion binding to host surfaces (see section 2.5) and administering compositions of immunoglobulins directed against these adhesions to provide passive immunity serves to lessen or prevent disease induced by the microorganism.

17. The vaccine compositions administered to a host mammal, which includes human hosts, for the generation of immunoglobulin compositions (see section 2.4) are taught to be directed to a family of adhesins (see section 1.2.1) and comprises not only collagen binding protein adhesion, but additional peptides, antigens and outer membrane preparation (see Hook et al section 2.4). Clearly Hook teaches the generation of polyclonal antibodies that will inhibit colonization of both staphylococcus and streptococcus pathogens (see section 2.2) and specifically teaches the combination of a vaccine adhesion antigens for the generation of immunoglobulins that comprises collagen, fibronectin and fibrinogen binding proteins (see section 4.25),

18. Hook et al discloses that polyclonal antibodies directed against several bacterial-binding proteins has been generated (see section 5.3.9.1). ClfA, (see section 5.3.7) is taught for passive immunization. Therefore, the examiner did not mischaracterize the Hook et al patent by sighting unrelated sections, because the reference teaches compositions of immunoglobulins that comprises a plurality of antigen binding specificities to include (see col. 30, lines 51-52 and col. 50, line 23; col. 51, lines 26-27) ClfA, collagen binding protein, fibronectin binding protein and

fibrinogen binding protein (see section 4.25; section 2.4; section 1.21; section 2.2; section 4.24.1).

19. Hook et al clearly teaches, suggests, provides guidance and motivation for the generation of human donor immunoglobulin directed to ClfA, collagen binding protein, fibronectin binding protein and fibrinogen binding protein (they are referred to as MSCRRAMMs). The examiner's responses set forth in paragraphs 23-31, pages 7-9 of paper number 20040804 are incorporated herein by reference. The claims remain or are rejected under 35 USC 103(a) as being obvious over Hook et al.

New combination of claim limitations/New Grounds of Rejection

Claim Rejections - 35 USC § 101

20. 35 U.S.C. 101 reads as follows: Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

a. Amended claims 11,22,29 and 36 now recite the phrase "A human immunoglobulin composition"; the immunoglobulin is not isolated and purified and therefore reads on a product of nature. The claimed invention is directed to non-statutory subject matter.

Claim Objections

21. Claims 12-21, 30-35, 41 and 54 are objected to because of the following informalities:

22. Claims 12-21 and 30-35 and 41 have been amended to recite the phrase "a human immunoglobulin" in the preamble of the claim and the phrase "treating the donor blood or plasma to obtain a human immunoglobulin composition" in the body of the claim, while the first step of the claims recite step of "administering .....to a host donor". The definition of the

phrase "host donor" at paragraph [0168] of the instant Specification includes all "mature mammals". The claims are not internally consistent based upon the newly amended terms used to claim Applicant's invention. While the preamble provides antecedent basis for the recitation of "human immunoglobulin", the body of the claim through the recitation of the term "host donor" does not specifically provide for the species "human" through broadly defining the term to be any mature mammal. Claims 23-28 also, like claims 12-21 and 30-35 and 41, recite the term "human immunoglobulin" in the preamble, and the treating step of the claims, but obtain blood or plasma from donors, which is defined to be any mature mammal, and therefore recites a combination of claim limitations that is not internally consistent with the species (human) and genus (mature mammals) embodiments recited in the claims.

23. Claim 54 is objected to for reciting steps a), b) and c) while the first methods step after the term "comprising" is "obtaining" which is not labeled as a subparagraph of the claim. The method should recite 4 paragraphs a)-d). Additionally, claim 54 does not recite a period "." at the end of the claim, but recites a semi-colon ";" . The semi-colon should be amended to recite a "." period to be in correct claim format.

24. Appropriate correction is required.

Claim Rejections - 35 USC § 112

25. Claims 12-21, 23-28, 30-35 and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 12-21, 30-35 and 41 recite the methods step of

"administering" ....to a **host donor,** or in the case of claims 23-28 "obtaining blood or plasma samples from **donors"** which is defined to be any mature mammal (definition provided by the instant Specification paragraph [0168]), and then "treating the donor blood or plasma to obtain **a human** immunoglobulin composition". The examiner upon consideration of the guidance and teaching of the instant Specification, could not find original descriptive support for treating a donor blood or plasma from any mature mammal to obtain a composition of human immunoglobulin when the donor blood or plasma is obtained from a mature mammal, such as a cow. No specific treatments evidence original descriptive support for changing a donor composition from one type of immunoglobulin of a mature mammal into human immunoglobulin. No specific sequences for the humanization of an immunoglobulin composition evidence original descriptive support in the instant Specification. Therefore claims 12-21, 23-28, 30-35 and 41 recite a combination of claim limitations that do not evidence original descriptive support and set forth New Matter.

26. Claim 55 is rejected under 35 USC 112, second paragraph for reciting the limitations "clumping factor protein B, SdrC, SdrD, SdrE, SdrF, SdrG, SdrH, CNA and EbpS" and depends from claim 54 which does not define the second adhesion to include clumping factor B or any of the other recited abbreviations; these terms lack antecedent basis in claim 54.

27. Claim 56 is rejected under 35 USC 112, second paragraph for reciting the term "Sdr protein" which lacks antecedent basis in claim 54 from which it depends as the term Sdr protein is not set forth in the Markush group of claim 54. There is insufficient antecedent basis for this limitation in claim 54.

Conclusion

28. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Nilsson et al (1998) analyzed 43 pathogenic strains of S. epidermidis and found 40 of the 43 strains to have the gene encoding S.epidermidis clumping factor (aka: fibrinogen-binding protein; see page 2671, col. 1, paragraph 2).

29. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

1. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
May 23, 2005

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